

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, EX REL.)

[PARTY X] )

Plaintiff, )

-v- )

[PARTY Y] )

Defendants. )

) **SEALED COMPLAINT**

) **DO NOT SERVE**

FILED IN CAMERA AND UNDER SEAL

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UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,  
*ex rel.* RICHARD ADRIAN,  
  
Relator/Qui Tam Plaintiff,

-v-

OTISMED CORPORATION  
1600 Harbor Bay Pkwy  
Suite 200  
Alameda, CA 94502

c/o Registered Agent  
Charlie Chi  
527 Ivy Street  
San Francisco, CA 94102

)  
)  
) Civil Action No. \_\_\_\_\_(SEALED)

) COMPLAINT AND JURY DEMAND

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) TO BE FILED UNDER SEAL

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) DO NOT SERVE

and )  
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STRYKER CORPORATION )  
2825 Airview Blvd. )  
Kalamazoo, MI 49002 )  
)  
c/o Registered Agent )  
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)  
and )  
)  
)  
HOWMEDICA OSTEONICS )  
CORPORATION d/b/a/ STRYKER )  
ORTHOPAEDICS )  
325 Corporate Drive )  
Mahwah, NJ 07430 )  
)  
c/o Registered Agent )  
The Corporation Trust Company )  
820 Bear Tavern Road )  
West Trenton, NJ 08628 )  
)  
and )  
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)  
BIOMET, INC. )  
56 East Bell Drive )  
P.O. Box 587 )  
Warsaw, IN 46582 )  
)  
c/o Registered Agent )  
Corporate Creations Network )  
105 East Jefferson Blvd )  
Suite 800 )  
South Bend, IN 46601 )  
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and )  
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BIOMET ORTHOPEDICS, LLC )  
56 East Bell Drive )  
P.O. Box 587 )  
Warsaw, IN 46582 )

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c/o Registered Agent )  
 Corporate Creations Network )  
 105 East Jefferson Blvd )  
 Suite 800 )  
 South Bend, IN 46601 )  
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 and )  
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 JOHN DOES 1-100, )  
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 Defendants. )  
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This is an action by *qui tam* Relator Richard Adrian ("Relator"), through the undersigned counsel, made on behalf of himself and the United States of America ("United States") to recover damages and penalties arising from Defendants OtisMed Corporation, Stryker Corporation, Howmedica Osteonics Corporation d/b/a Stryker Orthopaedics, Biomet, Inc., Biomet Orthopedics, LLC, and John Does 1-100 (collectively "Defendants") using, making, conspiring, presenting, or causing to be presented false statements and claims to the government in violation of the False Claims Act, 31 U.S.C. § 3729 *et seq.* (and as amended in 2009). The Defendants wrongfully conspired, obtained, or caused others to obtain substantial funds from government healthcare programs, including but not limited to Medicare, Medicaid, and TRICARE/CHAMPUS, through false claims and false statements made in connection with medical services or devices provided by Defendants or those they conspired with, or caused to be presented such false statements and claims since at least 2006. For instance, Defendants have engaged in the following improper conduct (or caused others to engage in and/or bill for such conduct), which violates the False Claims Act: (1) promoting, marketing, using, or causing to be used non-FDA approved medical devices; (2) promoting, marketing, using or causing to be used

off-label uses of medical devices or services; (3) promoting, marketing, engaging in, or causing to be engaged in a practice of unbundling medical products or services; and (4) promoting, marketing, engaging in, or causing to be engaged in a practice of violating Stark or anti-kickback rules or regulations. Such improper conduct resulted in billing government healthcare programs millions of dollars for knee replacements and hip replacements and resurfacings despite the fact that medical devices used in such services were not approved by the FDA. It has also resulted in millions of dollars in overbillings to the government by unbundling or separately billing MRI's that were integral parts of knee replacements and hip replacements and resurfacings that should not have been billed for separate and apart from these procedures.

Under the terms of the False Claims Act, this Complaint is to be filed in camera and under seal and is to remain under seal for a period of at least sixty days and shall not be served on the Defendants until the Court so orders. The Government may elect to intervene and proceed with the action within the sixty day time frame, or within any extensions of that initial sixty day period granted by the Court for good cause shown, after it receives both the Original Complaint and the Material Evidence submitted to it.

For his cause of action, the Relator alleges as follows:

#### **NATURE OF ACTION**

1. This is an action to recover treble damages and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729-3733.

2. Under the False Claims Act, a private person may bring an action in federal district court for himself and for the United States, and may share in any recovery. 31 U.S.C. § 3730(b). That private person is known as a "Relator" and the action that the Relator brings is called a *qui tam* action.

### **JURISDICTION**

3. This Court has subject matter jurisdiction to adjudicate this action under 28 U.S.C. §§ 1331 and 1345.

4. The Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because at least one of the Defendants transacts and has transacted business in this District.

### **VENUE**

5. Venue is proper in this District under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because at least one of the Defendants resides and/or transacts business in this District.

### **PARTIES**

6. The Relator brings this action on behalf of the United States, including its agency, the Department of Health and Human Services ("HHS") and its component, the Centers for Medicare & Medicaid Services ("CMS"), formerly the Health Care Financing Administration ("HCFA"), TRICARE/CHAMPUS, and all other federal healthcare programs.

7. The Relator also brings this action on behalf of himself, as permitted under the False Claims Act. Relator Richard Adrian is a citizen of the United States and a resident of the State of New Jersey. Richard Adrian has been an employee of Defendant Stryker Corporation from 1994-present in varying positions including branch sales manager for different geographic areas, area director of sales, and senior director of sales. As such, Richard Adrian has direct and independent knowledge, within the meaning of 31 U.S.C. § 3730(e)(4)(B), of the information on which the allegations set forth in this Complaint are

based. Richard Adrian is the original source of the allegations as defined in 31 U.S.C. § 3730(e)(4)(B). Richard Adrian has knowledge of the false statements, records and claims that Defendants knowingly falsely and fraudulently made or caused to be made in connection with medical services or devices provided by Defendants or those they conspired with.

8. Defendant OtisMed Corporation (“OtisMed”) is a privately held orthopedic technology company that provides solutions for complex clinical problems in bone and joint replacement. OtisMed’s focus is on developing and commercializing surgical solutions that are customized to each patient.

9. OtisMed’s initial offering was the *OtisKnee* product that enables surgeons to offer custom fit total knee replacement. With *OtisKnee*, surgeons can purportedly match the size and placement of the implant to the patient’s unique and normal (non-diseased) knee anatomy. This new “custom fit” approach enables surgeons to preserve more of the patient’s own bone and ligaments, which allegedly allows for better implant fit, alignment and longevity.

10. OtisMed’s *OtisKnee* product is based on OtisMed’s patent pending, proprietary *Shape-Match* technology that uses 3-D software that purportedly optimizes the size and placement of custom fit knee before surgery based on the patient’s own normal (non-arthritis) knee anatomy. Prior to surgery, a special MRI is performed to take defined measurements of the patient’s arthritic knee. OtisMed’s *Shape-Match* technology software then creates a 3-D image of the knee, which is then *Shape-Matched* to the anatomically correct virtual knee model. From this information, medical devices known as custom cutting

guides or blocks are created for surgeons to use during surgery in making bone cuts that are specific to the individual patient.

11. OtisMed has also developed hip replacement and hip resurfacing products that use surgical guide tools and other medical devices for use in total hip replacement and hip resurfacing surgeries.

12. Defendant Stryker Corporation ("Stryker") is a medical technology company offering a range of products in orthopedics and other medical specialties. Stryker's products include implants used in joint replacement, trauma, craniomaxillofacial, and spinal surgeries; biologics; surgical, neurological, ear, nose and throat and interventional pain equipment, endoscopic, surgical navigation, communications and digital imaging systems; as well as patient handling and emergency medical equipment.

13. Defendant Howmedica Osteonics Corporation d/b/a Stryker Orthopaedics ("Howmedica") operates as a subsidiary of Stryker and engages in the development, manufacture, and sale of orthopedic products and services. Howmedica offers hip, knee, upper extremity, trauma, and spinal systems, as well as bone cement and bone substitutes.

14. Specifically in relation to total knee replacements, Stryker and/or Howmedica have developed and/or designed the Triathlon Total Knee Replacement System that utilizes OtisMed's *OtisKnee* product and/or medical devices and technology to implant its own prostheses to allow for custom fit total knee replacements.

15. Hereafter, for convenience, Stryker Corporation, its predecessors, wholly and majority-owned subsidiaries – including Howmedica Osteonics Corporation d/b/a Stryker

Orthopaedics – equity joint ventures, and controlled affiliates will be collectively referred to as Stryker.

16. In 2008, Stryker's sales totaled \$6.718 billion, which put it among the 12 largest medical technology companies in the world.

17. In 2008, Stryker's orthopedic products yielded approximately \$5.5 billion in sales, or 82% of Stryker's total business.

18. Founded in 1977, Defendant Biomet, Inc. engages in the design, manufacture, and marketing of surgical and non-surgical products primarily used by orthopedic surgeons and other musculoskeletal medical specialists in the United States, Europe, and internationally. Biomet Inc.'s reconstructive products include knee, hip, shoulders, and extremity joint replacement systems, among others.

19. In September 2007, Biomet, Inc. became a private company when a consortium of private equity firms purchased Biomet, Inc. for \$11.4 billion.

20. Biomet Inc.'s 2009 fourth quarter consolidated earnings totaled \$635.6 million.

21. Defendant Biomet Orthopedics, LLC operates as a subsidiary of Biomet, Inc. and engages in the design, manufacture, and marketing of products primarily used by musculoskeletal medical specialists in surgical and nonsurgical therapy in the United States and internationally.

22. Specifically in relation to total knee replacements, Biomet, Inc. and/or Biomet Orthopedics, LLC have developed and/or designed the Vanguard Complete Knee System that

utilizes OtisMed's *OtisKnee* product and/or medical devices and technology to implant its own prostheses to allow for custom fit total knee replacements.

23. Hereafter, for convenience, Biomet, Inc., its predecessors, wholly and majority-owned subsidiaries – including Biomet Orthopedics, LLC – equity joint ventures, and controlled affiliates will be collectively referred to as Biomet.

24. Upon information and belief, there are additional Defendant John Doe entities that are wholly or majority-owned subsidiaries, equity joint ventures, and/or controlled affiliates of OtisMed Corporation, Stryker Corporation, and/or Biomet, Inc. that have participated in the fraud, but have yet to be identified.

#### THE FALSE CLAIMS ACT

25. The False Claims Act ("FCA") provides, in pertinent part, that:

(a)(1) Any person who (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); . . . or (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government

\* \* \*

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .

(b) For purposes of this section, the terms "knowing" and "knowingly" (A) mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate

ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information, and (B) require no proof of specific intent to defraud.

31 U.S.C. § 3729. The amount of civil penalties has been increased by amendments, which currently are set at \$5,500 and \$11,000 per claim.

### **THE MEDICARE PROGRAM<sup>1</sup>**

26. In 1965, Congress enacted Title XVIII of the Social Security Act to pay the costs of certain health care services for eligible individuals. 42 U.S.C. §§ 1395 *et seq.*

27. Medicare consists of two parts. Part A provides coverage for hospital costs, services rendered by skilled nursing facilities, home health care, and hospice care. Part B, on the other hand, provides coverage for physician services, outpatient hospital care, and other miscellaneous medical services such as physical and occupational therapy. *See* 42 U.S.C. §§ 1395j-1395w-4.

28. The U.S. Department of Health and Human Services (“HHS”) is an agency of the United States whose activities, operations, and contracts are paid from federal funds. The Centers for Medicare and Medicaid Services (“CMS”) is a division of HHS that is responsible for the administration and supervision of the Medicare program. For the purpose of administering Part A and Part B Medicare reimbursement claims, HHS contracts with private local insurance companies, known as “carriers” and “fiscal intermediaries,” to receive, review, and pay appropriate reimbursement claims related to services provided to Medicare beneficiaries. *See* 42 U.S.C. § 1395u.

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<sup>1</sup> The other government healthcare programs, such as TRICARE/CHAMPUS, have similar requirements and have similarly been defrauded by the Defendants. Whenever the term Medicare is used, the allegations also include that other government healthcare programs were similarly defrauded.

## MEDICARE COVERAGE AND REIMBURSEMENT

29. Medicare providers have a legal duty to familiarize themselves with Medicare's coverage and reimbursement rules, including those delineated in the Medicare Manuals. *Heckler v. Cmty. Health Serv. of Crawford County, Inc.*, 467 U.S. 51, 64-65 (1984).

30. The Medicare program is a defined benefits program whereby Congress has prescribed how beneficiaries become eligible to receive payment for products and services and defines the scope of those products and services. Medicare does not, however, identify all covered products, services, treatments, procedures or technologies.

31. Because no statutory list of specific medical devices or services to be covered exists, CMS, together with its contractors, have discretion to determine whether a specific device or service meets the definition of a benefit category and then whether the device or service using the device may be covered under the Medicare program.

32. To be eligible for Medicare coverage, a product or device not otherwise specified or expressly excluded by Congress must be "reasonable and necessary" for the treatment of illness or injury or to improve functioning of a malformed body member.

33. CMS has interpreted this "reasonable and necessary" standard to require a product or service, at a minimum, to be safe and effective, which in turn, means that unless exempt, it must have been approved or cleared for marketing by the FDA.

34. Since 1995, the categories of devices that may be covered under Medicare now include:

a. Devices approved by the FDA through the premarket approval (PMA) process;

b. Devices cleared by the FDA through the 510(k) process;  
and

c. FDA-approved investigational device exemption (IDE) category B (questions of safety and effectiveness of the device have been resolved) devices;

35. Statutory law and CMS policy, therefore, clearly preclude billing for non-FDA approved devices that have not been approved through the PMA, 510(k) or IDE processes.

36. Furthermore, to receive Medicare reimbursement, health care providers, suppliers, and practitioners must submit claims to the appropriate Medicare contractor. In addition to meeting administrative requirements, claims must describe the items and services for which payment is sought.

37. Medicare pays only for those services that are reasonable and necessary for the diagnosis or treatment of illness or injury. *See, e.g.*, 42 USC § 1395y(a)(1)(A).

38. Specifically, knee replacement services are billed under a diagnosis-related group (DRG) code. Depending upon the exact procedure, such as full or partial knee replacement, there are different DRG codes. Each DRG code entitles a provider to a set or fixed payment regardless of how much it costs the provider. In other words, a provider is paid a single predetermined amount per procedure that matches a specific DRG code.

39. Providers are not permitted to unbundle or separately bill for services necessary to the carrying out or performance of a single procedure and therefore cannot bill for each separate service of a single knee replacement procedure.

### **FACTUAL ALLEGATIONS**

40. From at least 2006 through the present, Defendants have knowingly engaged in systematic false and fraudulent schemes to defraud patients and government healthcare programs out of significant amounts of money.

41. Defendants have been knowingly using, making, conspiring, presenting or causing to be presented false statements and claims to the government in violation of the False Claims Act through a variety of improper schemes, including but not limited to falsely or fraudulently (1) promoting, marketing, using, or causing to be used unapproved medical devices; (2) promoting, marketing, engaging in, or causing to be engaged in the practice of using off-label uses of medical devices or services; (3) promoting, marketing, engaging in, or causing to be engaged in the practice of unbundling medical services; and (4) promoting, marketing, engaging in, or causing to be engaged in the practice of violating Stark or anti-kickback rules or regulations.

### **UNAPPROVED MEDICAL DEVICES**

42. According to Section 201(h) of the Federal Food Drug & Cosmetic Act, a medical device is defined as: “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes

through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.”

43. Any product that meets the above definition of “medical device” is regulated by the FDA and is subject to both pre-marketing and post-marketing regulatory controls.

44. Defendants, those they conspired with, and/or those they caused to submit false claims engaged in a variety of schemes to defraud the government by promoting, marketing, or using non-FDA approved medical devices in connection with custom fit knee replacement services.

45. Government rules prohibit the government from paying for medical devices that have not been approved by the FDA.

46. Upon information and belief, Stryker entered into an agreement to purchase OtisMed. The sale is contingent upon the FDA approving OtisMed’s medical devices that have already been used in numerous custom fit knee replacements by the Defendants.

47. Upon information and belief, during the summer of 2009, Stryker and/or OtisMed applied for FDA 510(k) approval of OtisMed’s knee replacement medical devices. As of the date of the filing of this Complaint, the FDA has not approved any of OtisMed’s custom fit knee replacement medical devices under either the PMA, 510(k), or IDE processes. Nevertheless, Defendants have billed the government millions for custom fit knee replacement procedures performed improperly utilizing OtisMed’s non-FDA approved knee replacement medical devices.

48. Furthermore, upon information and belief, Defendants did not provide or include all relevant information to the FDA in the 510(k) application, including all Medical Device Reports, data or reports concerning any problems, or complaints by patients or healthcare providers regarding knee replacements that utilized the unapproved medical devices. In addition, they improperly gave others the wrong impression that the medical devices were approved; they concealed patient complaints or MDRs; and they improperly caused reports to be made identifying only the positive procedures and downplaying or concealing unfavorable results. Moreover, Defendants misstated the nature and classification of such medical devices. Such concealments and false information about the medical devices constitutes fraud which would act to void any potential FDA approval.

49. Upon information and belief, OtisMed also has developed hip replacement and/or hip resurfacing products that require use of surgical guide tools and other medical devices for use during the surgical procedures. Defendants, those they conspired with, and/or those they caused to submit false claims engaged in a variety of schemes to defraud the government by promoting, marketing, or using non-FDA approved medical devices in connection with these hip replacement and resurfacing services.

#### **PROMOTING UNAPPROVED DEVICES**

50. Stryker and OtisMed have entered into an agreement in which Stryker and OtisMed would jointly or cooperatively promote or market to healthcare providers certain knee replacement medical devices manufactured, produced, provided or sold by OtisMed and/or Stryker.

51. Biomet and OtisMed have entered into a similar agreement in which Biomet and OtisMed would jointly or cooperatively promote or market to healthcare providers certain knee replacement medical devices manufactured, produced, provided or sold by OtisMed and/or Biomet.

52. Upon information and belief, OtisMed divided the country into two, whereby Stryker would promote or market in the Eastern portion of the United States and Biomet in the Western portion of the United States.

53. Defendants were aware or should have been aware that OtisMed had never sought to obtain FDA approval for its medical devices used in knee replacements. Nevertheless, the Defendants continued to promote, market, or co-market use of such unapproved medical devices. In addition, Defendants promoted or engaged in off-label uses of such medical devices.

54. OtisMed's medical devices were an integral and necessary part of the custom fit knee replacement procedures and systems that were promoted, marketed, or co-marketed by the Defendants.

55. OtisMed engaged in co-marketing and promotional efforts regarding unapproved medical devices with both Stryker and Biomet. This included internal training and marketing sessions, jointly providing materials to health care providers, and/or providing materials on behalf of one another. Examples also include, but are not limited to, the following:

a. OtisMed provided to Stryker and Biomet sales and management employee materials for distribution to hospitals, surgeons and MRI centers.

b. At the request of Stryker and/or Biomet, employees were trained both in groups and individually to sell OtisMed technology together with implant products of Stryker and/or Biomet. This included OtisMed videos, literature, and bone models, which were jointly utilized.

c. OtisMed used Stryker and/or Biomet employees to help promote surgeon training sessions, *i.e.* dinner meetings, and other promotional activities, such as the OtisMed "cocktail party" sales presentation at the American Academy of Orthopedic Surgeon meetings during 2007 and 2008.

d. OtisMed provided marketing services for hospital and surgeons through Stryker and/or Biomet sales force employees and an independent marketing company hired by OtisMed. This service was to help promote the use of more OtisMed devices, more MRIs, and more knee implants from Stryker or Biomet.

56. Groups of employees of the Defendants met together to combine the various marketing and promotional activities that had been used over the past several years to prepare a new set of training materials, which were used during a "dry run" to launch a large marketing push once the sale of OtisMed became official. The following training materials were used in the dry run, but also represent activities that the Defendants had been doing since at least 2006:

a. "Hospital Selling Guide." This undated overhead presentation was used, and is currently being used, by the Defendants as training materials for promoting the custom fit knee, a term used by the Defendants to promote their products and services. The presentation targets "Hospital Administrators, Internal Review Boards, Surgeons, and OR Staff." It directs Defendants' employees to target such healthcare providers and provides them with selling points as to why they should use products and services by the Defendants.

b. "Surgeon & Hospital Selling Strategies for OtisMed." This undated overhead presentation was used, and is currently being used, by the Defendants to show employees how to target surgeons and hospitals. It contains the OtisMed logo. At the conclusion of the presentation, the slide reads: "Push the marketing so it ties the physician and hospital to OtisMed."

c. "MRI Qualification Process." This undated overhead presentation was used, and is currently being used, by the Defendants to show employees how to target hospitals and how to use monetary incentives to convince them to use their products and services. It also recognizes that "there is currently no CPT code for the OtisMed sequence," and thus supporting knowledge

that the device is not approved by the FDA and therefore Defendants did not approach CMS to determine if it could be billed.

57. In addition, OtisMed routinely traveled with employees of Stryker and Biomet and conducted joint presentations to healthcare providers. They also frequently coordinated travel arrangements.

58. Stryker and Biomet pushed the sale of OtisMed because that would require the provider to use their total knee replacement products which are the only ones that were recommended to be used with OtisMed's *OtisKnee* product and/or medical devices and technology.

59. Statements made by Stryker managers regarding its knowledge that it was improperly promoting or marketing unapproved medical devices include:

a. "This is going to get us all in trouble." This was made during the summer of 2009 in response to a "dry run" of the training for Redwood, the company secret codename for OtisMed.

b. "I work with CMS all the time and if anyone ever blew the whistle we would be in deep trouble." Made after July 14-15, 2009 meeting.

c. "We should not be taking any trips that involve co-marketing with OtisMed." This was made in response to concerns that Stryker was improperly marketing OtisMed devices, which it knew were not FDA approved. However, despite the stated comments, Defendants continued to engage in joint training and joint marketing efforts.

d. "[T]hey should not be making travel plans with the OtisMed people." Another statement made in response to concerns that Stryker was improperly marketing OtisMed medical devices. Again, despite the stated comments, Defendants continued to engage in joint training and joint marketing efforts.

60. In short, Defendants knew that the knee replacement medical devices were not approved by the FDA, but continued to promote, co-promote, market, co-market, conspire

and otherwise cause others to use and submit false statements and claims to the government relating to knee replacements which used such non-FDA approved medical devices.

61. Upon information and belief, Defendants also knew that OtisMed's hip replacement and hip resurfacing medical devices were not approved by the FDA, but continued to promote, co-promote, market, co-market, conspire and otherwise cause others to use and submit false statements and claims to the government relating to hip replacements and hip resurfacings which used such non-FDA approved medical devices.

#### **UNBUNDLING MEDICAL SERVICES**

62. In addition, Defendants, those they conspired with, and/or those they caused to submit false claims engaged in a variety of schemes to defraud the government by marketing, promoting, or billing for parts or services, such as MRIs, that were a necessary or integral part of the knee replacement procedure and therefore received more government funds than they were entitled.

63. In order to bill for a MRI, a provider must show an independent diagnostic need. Generally, an MRI may be used by providers to help assess whether a knee replacement is needed. In those instances, the MRI may be a diagnostic event and billable. The allegations here, however, are far different. The Defendants encouraged providers to separately bill MRI's that were an integral and necessary part of their unique method of custom fit knee replacements.

64. OtisMed and the other Defendants are using what they refer to as a custom fit knees. It requires that a very specific MRI be taken in a precise manner in a specific timeframe. It is not used to diagnose that a knee replacement is needed. Rather, it is

conducted after a physician determines two separate things: (1) that a knee replacement is already needed; and (2) that it will use Defendants' products and services.

65. This special MRI is needed only for OtisMed products because OtisMed uses an MRI to design two custom cutting guides or blocks that fit the patient's anatomy. Without this special MRI, the custom cutting guides or blocks cannot be created/designed by OtisMed and, in turn, a physician therefore cannot use the Defendants' custom fit knee replacement systems.

66. This new method of custom fit knee replacements used by the Defendants is different than the rest of the providers in the United States. The processes used by the Defendants require an additional and special MRI. This special MRI determines the size of parts and precise places to cut bones for each individual patient. Defendants consider the MRI integral to using their products and performing a custom fit knee replacement using their systems. (*See supra* ¶ 10).

67. Even assuming that a physician might use an MRI in assessing whether a knee replacement is needed, it would still need to conduct another special MRI if it planned to use the Defendants' products. The Defendants have very specific and exacting requirements for the MRI and will not use a prior, diagnostic MRI. For instance, the special MRI needed to perform a knee replacement utilizing the Defendants' custom fit products must be conducted by a MRI entity certified by OtisMed. In short, only if a physician chose to use the Defendants' custom knee system would such an MRI be needed and in fact be essential. Conversely, if it chose another company's knee replacement components or process, an MRI would not be needed at all for the surgical knee replacement procedure.

68. Government programs pay a fixed fee utilizing a DRG code process for paying for knee replacements. In other words, providers receive a set or fixed amount depending upon the type of knee replacement, *i.e.* full or partial. This payment is not dependent upon the actual costs to the provider. For instance, if a DRG code pays providers \$10,000 for a certain knee replacement, the provider is paid that amount regardless of its costs. However, under this system of payment, a provider may not unbundle the procedures into separate components and submit requests for payment based on different steps or processes in the same knee replacement. This is known as unbundling, which is prohibited by government healthcare programs.

69. Here, Defendants devised or used schemes of promoting, marketing, or engaging in the practice of unbundling medical services and promoting, marketing, or engaging in the practice of violating Stark or anti-kickback rules or regulations. For instance, Defendants informed healthcare providers that they could and should consider billing for the special MRI, which is needed only if they use Defendants' products. In other words, it told the provider to go ahead and bill the full DRG code for the knee replacement procedure to the government, but to then submit an additional bill for the special MRI needed if it chose the Defendants' custom fit knee products.

70. When Defendants contacted some healthcare providers, they were told that their knee replacement devices and services cost more than others. Therefore, to induce them to use their products and services, Defendants devised fraudulent schemes to cause others to submit false bills to the government. For instance, they trained their employees to tell providers that this special MRI needed only if it used Defendants' products or process can be a revenue maker. Specifically, they encouraged healthcare providers to unbundle the special

MRI from the other aspects of the knee replacement procedure in order to receive more than the DRG code for the knee replacement procedure would permit. In other words, although this MRI was integral to the knee replacement procedure using OtisMed's medical devices, Defendants marketed and promoted that the providers unbundle the special MRI and submit two separated bills: one for the special MRI used in the knee replacement and another using the DRG code for the knee replacement procedure.

71. The Defendants trained its employees to show doctors just how much more they could bill the government if they unbundle the special MRI. They even suggested that they use related entities to perform the MRIs and thus engage in illegal self-referrals in violation of Stark and anti-kickback laws to make even more money.

72. Groups of employees of the Defendants met together to combine the various marketing and promotional activities that had been used over the past several years to prepare a new set of training materials, which were used during a "dry run" to launch a large marketing push once the sale of OtisMed became official. The following training materials were used in the dry run, but also represent activities that the Defendants had been doing since at least 2006:

a. "Hospital Selling Guide." This undated overhead presentation was used, and is currently being used, by the Defendants as training for promoting the custom fit knee, a term used by the Defendants to promote their products and services. The presentation targets "Hospital Administrators, Internal Review Boards, Surgeons, and OR Staff." It identifies the MRI as an "ancillary service opportunity" and goes on to suggest and show hospitals how to form in-house MRI systems to further increase their revenue. It goes on to list as a selling point that hospitals could bill an average of \$800 per MRI and make an extra \$200,000 for such MRI billings for every 200 knee replacements.

b. "Surgeon & Hospital Selling Strategies for OtisMed." This undated overhead presentation was used, and is currently being used, by the

Defendants to show employees how to target surgeons and hospitals. It contains the OtisMed logo. It also contains similar language about promoting MRI "ancillary service opportunity."

c. "MRI Qualification Process." This undated overhead presentation begins by recognizing that the MRI used for the knee replacement utilizing their new approach "is an integral part of *OtisKnee* Process." It also recognizes that a "Hospital will likely opt to recoup revenue." In addition, the overhead states that "there is currently no CPT code for the OtisMed sequence." Moreover, the overhead states: "MRI is billed to patients insurance."

73. Specifically, the "Hospital Selling Guide" presentation states, in relevant part:

Selling Points: Traditional vs CFK (Custom Fit Knee)

**ANCILLARY SERVICE OPPORTUNITY**

**MRI Volume** – The 3-D imaging required for pre-operative planning, positioning, and creation of the custom cutting guides provides for increased Magnetic Resonance Imaging ("MRI") volume.

**ROI** – Based on the increased demand for this type of imaging, the facility has the potential to reduce fixed costs per exam while improving return on investment of an in-house MRI system.

74. Statements made by Stryker managers regarding its knowledge that it was improperly promoting or marketing the unbundling of MRI and other services or devices include:

a. "We should not discuss MRI reimbursement which will get us all in trouble since it is a clear violation." Made after July 14-15, 2009 meeting.

b. "My hospitals are making money with OtisMed MRI reimbursement and even saving on operating room drugs." Made by sales manager.

c. "We will be in major trouble if we continue to market reimbursements like we are showing in our slides and discussions at this meeting." Made after July 14-15, 2009 meeting.

75. Defendants did not approach CMS or its agents to determine if a provider could bill separately for the special MRI. Nor did Defendants ask whether its custom fit knee replacement procedure, which utilized non-FDA approved medical devices, could be billed at all or under which particular DRG code.

76. In short, Defendants knew that the MRIs were an integral part of the knee replacements utilizing OtisMed products and services, yet they promoted, co-promoted, marketed, co-marketed, conspired and otherwise caused others to submit false statements and claims to the government by unbundling the MRI and other items and billing them as separate services or products, therefore enabling the providers to receive more Medicare reimbursement than they were entitled. The Defendants also told providers that they can make even more money if they used a related entity to perform the MRIs and thus engage in self-referrals, which would violate Stark and anti-kickback rules.

77. Upon information and belief, special MRIs were also an integral part of the hip replacements and hip resurfacing procedures utilizing OtisMed products and services, yet Defendants promoted, co-promoted, marketed, co-marketed, conspired and otherwise caused others to submit false statements and claims to the government by unbundling the MRI and other items and billing them as separate services or products, therefore enabling the providers to receive more Medicare reimbursement than they were entitled. The Defendants also told providers that they can make even more money if they form a related entity to perform the MRIs and thus engage in self-referrals, which would violate Stark and anti-kickback rules.

78. Upon information and belief, the alleged misconduct by Defendants Stryker and Biomet in paragraphs 40-77 also violated their respective corporate integrity type agreements

with the government stemming from a settlement occurring on or about September 2007, in which they agreed, among other things, to comply with compliance rules and monitoring. As a result, the government was additionally harmed.

**COUNT I**  
**VIOLATION OF THE FALSE CLAIMS ACT**  
**31 U.S.C. § 3729(a)(1) (1990)/31 U.S.C. § 3729(a)(1)(A) (2009)**

79. Relator incorporates by reference the allegations set forth in paragraphs 1 through 78 as though fully set forth herein.

80. As set forth above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment to officials of the United States Government in violation of 31 U.S.C. § 3729(a)(1) (1990) and 31 U.S.C. § 3729(a)(1)(A) (2009).

81. By virtue of the false or fraudulent claims made by the Defendants, the United States suffered actual damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty for each violation.

**COUNT II**  
**VIOLATION OF THE FALSE CLAIMS ACT**  
**31 U.S.C. § 3729(a)(2) (1990)/31 U.S.C. § 3729(a)(1)(B) (2009)**

82. Relator incorporates by reference the allegations set forth in paragraphs 1 through 78 as though fully set forth herein.

83. As set forth above, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim in violation of 31 U.S.C. § 3729(a)(2) (1990) and 31 U.S.C. § 3729(a)(1)(B) (2009).

84. By virtue of the false records or statements made by the Defendants, the United States suffered actual damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty for each violation.

**COUNT III**  
**VIOLATION OF THE FALSE CLAIMS ACT**  
**31 U.S.C. § 3729(a)(3) (1990)/31 U.S.C. § 3729(a)(1)(C) (2009)**

85. Relator incorporates by reference the allegations set forth in paragraphs 1 through 78 as though fully set forth herein.

86. This is a claim for civil penalties and treble damages under the False Claims Act.

87. By virtue of the acts described above, Defendants have knowingly conspired together to defraud the Federal Government by engaging in conduct including, but not limited to, promoting, co-promoting, marketing, co-marketing, or using non-FDA approved medical devices; promoting, co-promoting, marketing, co-marketing, or using off-label uses of medical devices or services; promoting, co-promoting, marketing, co-marketing, or engaging, or causing providers to engage, in a practice of unbundling medical services; and promoting, co-promoting, marketing, co-marketing, or engaging, or causing providers to engage, in a practice of violating Stark or anti-kickback rules or regulations.

88. Defendants' conspiracy defrauded the United States by causing or getting false or fraudulent claims allowed or paid.

89. As set forth in the preceding paragraphs, Defendants violated 31 U.S.C. § 3729(a)(3) (1990) and 31 U.S.C. § 3729(a)(1)(C) (2009) and have thereby damaged and

continue to damage the United States Government by their actions in an amount to be determined at trial.

**COUNT IV**  
**VIOLATION OF THE FALSE CLAIMS ACT**  
**31 U.S.C. § 3729(a)(7) (1990)/31 U.S.C. § 3729(a)(1)(G) (2009)**

90. Relator incorporates by reference the allegations set forth in paragraphs 1 through 78 as though fully set forth herein.

91. As set forth above, Defendants knowingly made, used, or caused to be made or used false records or statements material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government in violation of 31 U.S.C. § 3729(a)(7) (1990) and 31 U.S.C. § 3729(a)(1)(G) (2009).

92. By virtue of the false records or statements made, used, or caused to be made or used by the Defendants, the United States suffered actual damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty for each violation.

**PRAYER FOR RELIEF**

WHEREFORE, the United States and Relator demand that judgment be entered against the Defendants and in favor of the Relator and the United States as follows:

1. On the First, Second, Third and Fourth Causes of Action under the False Claims Act, as amended, for the amount of the United States' damages, multiplied by three as required by law, and such civil penalties as are permitted or required by law;

2. That the Relator be awarded the maximum share amount allowed pursuant to 31 U.S.C. § 3730(d);

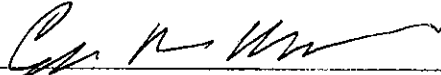
3. That the Relator be awarded all costs and expenses of this action, including attorney fees, expenses and costs as permitted by 31 U.S.C. § 3730(d).

4. That the United States and Relator receive all such other relief as may be just and proper.

**REQUEST FOR TRIAL BY JURY**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Respectfully submitted,



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*Attorneys for Relator Richard Adrian*

**CERTIFICATE OF SERVICE**

The undersigned certifies that on this 2nd day of October, 2009, a copy of the foregoing Complaint and a Disclosure Statement were served on the individuals below via Fed Ex

Delivery:

Hon. Ralph J. Marra, Jr.  
Newark United States Attorney's Office  
Peter Rodino Federal Building  
970 Broad Street  
Suite 700  
Newark, NJ 07102

Hon. Eric H. Holder, Jr.  
Attorney General of the United States  
5111 Main Justice Building  
10th & Constitution Ave. N.W.  
Washington, DC 20210



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Colin R. Robinson